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| 09/995,785 | 11/29/2001 | Alex Azhayev | 005416.00004 | 9129 |

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EXAMINER

BAKER, MAURIE GARCIA

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1639

DATE MAILED: 10/07/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/995,785

Applicant(s)

Azhayev et al

Examiner

Maurie G. Baker, Ph.D.

Art Unit

1639



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 17, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 and 64-73 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 21-34, 41-53, and 64-73 is/are rejected.
- 7) ☒ Claim(s) 15-20 and 35-40 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

1. The Response filed July 17, 2003 (Paper No. 11) is acknowledged. Claim 45 was amended, claims 54-63 were cancelled and claims 64-73 were added. Therefore, claims 1-53 and 64-73 are pending.

2. The amendment of claim 45 to limit the claim to the elected invention is noted with appreciation. Although there is still currently no allowable generic claim, in the interest of compact prosecution the search has been expanded in this action to all species, elected and non-elected, and thus claims 1-53 and 64-73 are examined in this action.

Status of Rejections

3. The rejection under 35 U.S.C. 112, first paragraph is maintained; applicant's arguments are addressed following the rejection. However, please note the examiner's comments regarding potential allowable subject matter in paragraph 13 (and also indication of allowable claims in paragraph 14).

Maintained Rejections Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-14, 21-34, 41-53 and 64-73 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific supported compounds on pages 10-11 of the instant specification, does not reasonably provide enablement for all compounds (supported and unsupported) encompassed by the instant claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

It is clear from applicant's specification how one might practice this invention when using the specific supported compounds on pages 10-11 of the instant specification; however, there is insufficient guidance as to how to make/use any compound (supported or unsupported) encompassed by the instant claims. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include, but are not limited to:

- (1) the breadth of the claims;
- (2) the nature of the invention;
- (3) the state of the prior art;
- (4) the level of one of ordinary skill;
- (5) the level of predictability in the art;
- (6) the amount of direction provided by the inventor;
- (7) the existence of working examples; and
- (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

(1-2) The breadth of the claims and the nature of the invention: The claims are drawn to supports and articles having a generic formula. The formula

encompasses a wide variety of compounds of varying structure and the claims (e.g. 45) also encompass unsupported compounds. This represents very broad scope. (3 and 5) The state of the prior art and the level of predictability in the art: Compounds that are used as linkers for solid supported synthesis were known at the time of filing; however, only limited numbers of such compounds were known and the specification gives *no* guidance to permit one of skill in the art to devise strategies for making and using any compound falling within the instant claims for such a purpose. The structures of possible variants are sufficiently diverse and one of ordinary skill would not be able to predict their structures. The linkage chemistry to supports ("base material") of different structure as well as the linkage of oligonucleotides through different functionalities would be unpredictable. (4) The level of one of ordinary skill: The level of skill would be high, most likely at the Ph.D. level. However, such persons of ordinary skill in this art, given its unpredictability, would have to engage in undue (non-routine) experimentation to carry out the invention as claimed. (6-7) The amount of direction provided by the inventor and the existence of working examples: Applicants have only provided a very limited number of examples of supports and articles encompassed by the instant claims. Applicant's claimed scope of supports and articles represents only an invitation to experiment regarding possible compounds and their use. Specifically, the instant specification fails to identify that structure which is required for the claimed activity. (8) The quantity of experimentation needed to make or use the invention based on the content of

the disclosure: The instant specification does not provide to one skilled in the art a reasonable amount of guidance with respect to the direction in which the experimentation should proceed in making and using the full scope of the claimed supports/articles. Note that there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed. *In re Vaeck*, 947 F.2d 488, 496 & n.23, 20 USPQ2d 1438, 1445 & n.23 (Fed. Cir. 1991). Therefore, it is deemed that further research of an unpredictable nature would be necessary to make or use the invention as claimed. Due to the inadequacies of the instant disclosure, one of ordinary skill would not have a reasonable expectation of success and the practice of the full scope of the invention would require undue experimentation.

Response to Arguments

6. Applicant's arguments filed July 17, 2003 have been fully considered but are not found persuasive. The examiner's rationale is set forth below.

7. Applicants state that the "Office Action fails to provide a single technical reason or a hint of objective evidence to rebut the presumption of enablement" (Response, page 17). The examiner respectfully disagrees. The examiner states several technical reasons for the lack of enablement for the full scope, for example:

"Compounds that are used as linkers for solid supported synthesis were known at the time of filing; however, only limited numbers of such compounds were known and the specification gives *no* guidance to permit one of skill in the art to devise strategies for making and using any compound falling within the instant claims for such a purpose. The structures of possible variants are sufficiently diverse and one of ordinary skill would not be able to predict their structures. The

linkage chemistry to supports ("base material") of different structure as well as the linkage of oligonucleotides through different functionalities would be unpredictable."

and

"Applicants have only provided a very limited number of examples of supports and articles encompassed by the instant claims. Applicant's claimed scope of supports and articles represents only an invitation to experiment regarding possible compounds and their use. Specifically, the instant specification fails to identify that structure which is required for the claimed activity."

8. Thus, as stated above, persons of ordinary skill in this art, given its unpredictability, would have to engage in undue (non-routine) experimentation to carry out the invention as claimed. With respect to unpredictability, the following is noted. The "predictability or lack thereof" in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art. Specifically, one of the most important points from the rejection is that the linkage chemistry to supports ("base material") of different structure as well as the linkage of oligonucleotides through different functionalities would be unpredictable. The examiner's position is that one skilled in the art could not readily anticipate the effect of a change within different chemical attachments to the broadly claimed "polymeric base material" or "silica base material" and their use. The independent claims are completely non-limiting as to the specific structure of the linkage to the base material, and even its position (i.e. can be position A or B).

9. Also, in cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved. See *In re Fisher*, 57 CCPA 1099, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Additionally, the Board has held on the issue of unpredictability that "... the unpredictability of an art area alone may be enough to create a reasonable doubt as to the accuracy of statements in the specification." *Ex parte Singh*, 17 U.S.P.Q.2d 1714, 1716 (B.P.A.I. 1990).

10. Applicants state that no working examples are required (Response, page 18) and that the examples provided do provide sufficient guidance to enable the claims for their full scope. The examiners position is as follows: while it is true that an example is not required, it is often necessary to provide description and enablement for broad claims. Thus, in applications directed to inventions in arts where the results are unpredictable, the disclosure of a limited number of species usually does not provide an adequate basis to support generic claims. *In re Soll*, 97 F.2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). Also see MPEP 2164.02. Thus, the examiner maintains that there is not sufficient disclosure to teach those of ordinary skill how to make and use the invention as broadly as it is claimed.

11. It is also noted that in some of the claims (e.g. claim 45 and claims dependent thereon), unsupported compounds are also set forth. There is simply insufficient

guidance as to how to make and use such compounds, as there are no examples whatsoever regarding compounds not attached to a solid support.

12. Please also note that arguments of counsel alone cannot take the place of evidence in the record once an examiner has advanced a reasonable basis for questioning the disclosure. See *In re Budnick*, 537 F.2d at 538, 190 USPQ at 424; *In re Schulze*, 346 F.2d 600, 145 USPQ 716 (CCPA 1965); and *In re Cole*, 326 F.2d 769, 140 USPQ 230 (CCPA 1964). For example, in a case where the record consisted substantially of arguments and opinions of applicant's attorney, the court indicated that factual affidavits could have provided important evidence on the issue of enablement. See *In re Knowlton*, 500 F.2d at 572, 183 USPQ at 37, and *In re Wiseman*, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979). Therefore, for these reasons and the reasons of record, the rejection is maintained.

13. However, the following is noted to try to advance prosecution. As stated in the rejection, applicant's specification clearly enables the supported compounds denoted on pages 10-11. These compounds are generally represented in the claims by instant claims 3, 8, 23 and 28. However, these claims are not set forth in a limiting manner, that is, the claims recite that "substituent A [or B] includes the following substituent" (emphasis added). The use of the term 'includes' is open-ended and thus the claims remain rejected. Limitation of independent claims 1 and 21 to the situation where (1) A is the substituent of claim 3/23 and B is an acyl group or aroyl group **OR** (2) B is the substituent of claim 8/28 and A is H, alkyl or aryl would be likely to bring favorable consideration. Also see

paragraph 14 below (indication of allowable claims drawn to particular species of supported compounds).

Status of Claims/Conclusion

14. No claims are allowed. However, claims 15-20 and 35-40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Serial Number: 09/995,785
Art Unit: 1639

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner is on an increased flextime schedule but can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.

17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.
October 5, 2003


MAURIE GARCIA BAKER PH.D.
PRIMARY EXAMINER